REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

Appreciation is expressed to Examiner Deak for pointing out that the Patent Office's file does not include a copy of form PTO-1449 submitted with the earlier filed Information Disclosure Statement. Attached is a copy of such form to allow the Examiner to indicate consideration of the cited references.

Appreciation is also expressed to Examiner Deak for the indication that Claim 24 would be allowable if rewritten in independent form.

In light of the earlier imposed restriction requirement, Claims 30-67 directed to the non-elected inventions have been canceled and have been made the subject of divisional applications. Thus, the only claims currently pending in this application are Claims 1-29, with Claim 1 being the only independent claim.

The Official Action sets forth an obviousness-type double patenting rejection of various claims in this application based on claims in U.S. Patent No. 6,802,892 and U.S. Patent No. 6,719,715. In response, Applicant submits herewith Terminal Disclaimers disclaiming the portion of the term of the patent issuing from this patent that would extend beyond the patent term of such patents. The submission of these Terminal Disclaimers should not be construed as an indication that applicant agrees with the propriety of the obviousness-type double patenting rejections.

The Official Action also sets forth a rejection of independent Claim 1 and various dependent claims as being unpatentable over U.S. Patent No. 6,142,971 to *Daoud et al.* in view of U.S. Patent 5,052,382 to *Wainright.*

The claims at issue in this application are directed to an apparatus for conditioning mammalian blood for subsequent use in a medical procedure. The conditioning of the blood involves subjecting the blood to at least an ozone/oxygen mixture. The claimed apparatus comprises a cabinet having a secure environment and a door providing the only access to the secure environment, an input system for transporting a blood charge from a source to the cabinet, a flask removably contained in the secure environment and coupled to the input system to receive the charge, and stressors coupled to the cabinet and positioned for operation to create a conditioned charge in the flask, wherein the stressors comprise an oxygen source removably coupled to the cabinet and an ozone generator coupled to the oxygen source to generate an ozone/oxygen mixture for delivery to the flask. An output system is coupled to the flask and includes a receiver for the conditioned charge. In addition, a control system is operable upon closing the door to lock the door and to then automatically condition the charge and cause the charge to move from the flask to the receiver, whereby a charge from the input system is conditioned and delivered to the receiver, the door is then unlocked and the conditioned charge is ready to be removed and used to complete the medical procedure.

Daoud et al. discloses a system for generating a gas-supersaturated fluid and delivering the fluid at high pressure for enriching blood with the gas-supersaturated fluid or to reduce or prevent localized ischemia by delivering the gas-supersaturated fluid downstream of a balloon angioplasty site. The disclosed system includes a high pressure fluid delivery system 10 comprising a fluid assembly 20 to hold a fluid to be gas-supersaturated and delivered, and a drive assembly 30 for delivering such gas-supersaturated fluid at a high delivery pressure. The fluid assembly 20 and the drive

assembly 30 are mounted in a housing 40. The fluid assembly 20, includes a cylinder 50 containing a disposable container 70. The container 70 is adapted to receive a fluid of physiologic saline or lactated ringers solution.

As discussed in column 2, lines 11-19 of *Daoud et al.* and in the discussion beginning in line 47 of column 4, to gas-supersaturate the fluid in the container 70, the fluid assembly 20 (which includes the cylinder 50 containing the disposable container 70) is removed from the housing 40 and is positioned in a support structure 200 as illustrated in Fig. 11. After introducing the fluid into the container 70, oxygen is introduced into the container 7 at a pressure that is the same or slightly above the desired resultant partial pressure of the gas. Following gas-supersaturation, the fluid assembly 20, including the cylinder 50 containing the container 70, is removed from the support structure 200 and returned to the housing 40 so that the gas-supersaturated fluid can be delivered to the patient.

One of the differences between the claimed apparatus at issue here and the disclosure in *Daoud et al.* is that the claimed apparatus includes stressors coupled to the cabinet to create a conditioned charge in the flask, with the stressors comprising an oxygen source removably coupled to the cabinet, and an ozone generator coupled to the oxygen source to generate an ozone/oxygen mixture for delivery to the flask. Thus, the stressors are coupled to the cabinet so that with the flask in the secure environment of the cabinet, the ozone/oxygen mixture is delivered to the charge in the flask to condition the charge. This is not the case with the system described in *Daoud et al.* The purported stressor in *Daoud et al.* is not coupled to the housing 40 and does not include an oxygen source removably coupled to the housing 40 and an ozone generator coupled to the oxygen source to generate an

ozone/oxygen mixture for delivery to the container 70. As discussed above, oxygen is introduced into the container 70 of the fluid assembly 20 after the fluid assembly 20 (which includes the cylinder 50 containing the disposable container 70) has been removed from the housing 40. Thus, the oxygen source in *Daoud et al.* cannot be said to be coupled to the housing 40 in the claimed manner for introducing oxygen into the container 70 in the housing 40.

In addition, independent Claim 1 recites the cabinet having a secure environment together with a control system that is operable upon closing the door of the cabinet to lock the door and automatically condition the charge and cause the charge to move from the flask to the receiver. The Official Action states that the recited operational characteristics of the control system constitute a recitation of intended use. Claim 1 has been amended to change the original recitation of the control system to control means. This amendment merely recites in a different manner that which was originally set forth in the claim. Quite clearly, *Daoud et al.* does not disclose a control system/control means that is operable upon closing the door to lock the door and automatically condition the charge in the flask and cause the charge to move from the flask to the receiver. In the context of the apparatus at issue here which conditions mammalian blood, there is a need for a secure environment, and so the need to lock the door upon closing and automatically condition the charge and cause the charge to move from the flask to the receiver is a relevant concern. This same need for a secure environment within the cabinet and a control system/means as claimed does not exist in the context of the apparatus described in *Daoud et al.*

A still further point of distinction involves the recitation in Claim 1 of the

ozone generator coupled to the oxygen source to generate an ozone/oxygen mixture for delivery to the flask. As the Official Action correctly notes, *Daoud et al.* does not discloses an ozone generator coupled to the oxygen source to generate an ozone/oxygen mixture for delivery to the flask. In this regard, the Official Action relies upon the disclosure in *Wainwright* which describes an apparatus for carrying out the controlled generation and administration of ozone. It is respectfully submitted that a *prima facie* case of obviousness has not been established as it has not been shown that an ordinarily skilled artisan would have been motivated to utilize *Wainwright's* ozone generator in the system described in *Daoud et al. Daoud et al.* describes using oxygen to produce a gas-supersaturated solution. Nowhere does *Daoud et al.* discuss or suggest that using a ozone/oxygen mixture would be useful or beneficial in producing a gas-supersaturated fluid. Certainly, the very general comment at the top of column 5 of *Daoud et al.* describing that gas introduced into the container is, *for example*, oxygen is hardly a specific teaching that would lead one to use an ozone/oxygen mixture to gas-supersaturate the fluid. Further, *Wainwright* does not mention that the disclosed ozone generator should be used to produce a gas-supersaturated fluid. It is thus respectfully submitted that a person of ordinary skill in the art, studying the disclosures in *Daoud et al.* and *Wainwright*, would not have motivated to add an ozone generator to the system disclosed in *Daoud et al.*

For at least the reasons set forth above, it is respectfully submitted that the claimed apparatus recited in independent Claim 1 and the various dependent claims is patentable distinguishable over a combination of the disclosures in *Daoud et al.* and *Wainwright.*

The dependent claims are allowable at least by virtue of their dependence from allowable independent Claim 1. These dependent claims also define further distinguishing characteristics associated with the claimed apparatus. For example, Claim 7 recites the probe that is coupled to the connector assembly of the flask and having an input lumen coupled to the input system to deliver the charge into the internal volume of the flask main portion and an output lumen coupled to the output system for delivering the conditioned charge to the output system. Claim 9 recites a further lumen and a temperature sensor positioned in such further lumen to monitor the temperature of the charge. The Official Action comments that the tubing disclosed in *Daoud et al.* corresponds to the claimed probe and also observes that it would have been obvious to position the thermistors described in the bottom portion of column 7 of *Daoud et al.* in such lumen. However, it is noted that Claim 7 recites an input lumen coupled to the input system and an output lumen coupled to the output system, while Claim 9 recites a further lumen, with the temperature sensor positioned in such further lumen. By way of example referring to the illustrated embodiment of the apparatus at issue here, Fig. 5 shows that the probe 65 includes a charge intake lumen 104, a charge return lumen 109 and a lumen 104 that holds a temperature sensor 138. There is no disclosure in *Daoud et al.* of three lumens as claimed, one of which includes a temperature sensor.

Claim 8 depends from Claim 7 and recites that the probe includes, in addition to the lumens recited in Claim 7, a gas lumen coupled to one of the stressors to deliver a gas stressor to the charge. No such gas lumen is disclosed in *Daoud et al.*

The Official Action rejects Claims 16 and 17 as being unpatentable over *Daoud et al.* in view of *Wainright*, and further in view of *Davidner*. Applicant

respectfully submits that a person of ordinary skill would not have been led to do that which is recited in Claims 16 and 17 based on the disclosures in these three references. Adding *Davidner's* infrared and/or ultraviolet light sources to the apparatus described in *Daoud et al.* would not result in the claimed subject matter since *Davidner* exposes cells to infrared and/or ultraviolet light in line 170 (treatment loop A), and not in a cylinder or flask. In the claimed apparatus at issue here, the stressors are coupled to the cabinet to create a conditioned charge in the flask. Further, to the extent *Davidner* discloses infrared and/or ultraviolet light treatment, it is in connection with the treatment of blood. The apparatus disclosed in *Daoud et al.* does not treat blood cells, but rather gas-supersaturates physiologic saline or lactated ringers solution. Thus, one would not view the disclosure in *Davidner* to be particularly relevant to the apparatus described in *Daoud et al.* Therefore, Claims 16 arid 17 are further patentable over the cited prior art.

The Official Action also sets forth a rejection of Claims 20 - 22 as being unpatentable over *Daoud et al.* in view of *Wainright* and further in view of *Kobashi et al.* Column 7, lines 37- 52 of *Daoud et al.* describe that the fluid is pushed out of the container 70 by applying a pressure of the fluid via the piston 52. The pressure is determined by the delivery rate and the size of the system fluid delivery device 122. Additionally, *Daoud et al.* teaches a system fluid delivery device 122 such as an infusion device comprising a 400cm flex spiral tubing (column 8, lines 23-30) to deliver high volumes of fluid to the patient, such as 275cc (column. 1, lines 25-29 and column 7, lines 31-33). On the other hand, at column 9, lines 5-8, *Kobashi et al.* describes dispensing fluid at a high speed (e.g. 4.1 µl/s). With these different objectives, it is respectfully submitted that there would have been no motivation for

person of ordinary skill to carry out the modification proposed in the Official Action. Further, it has not been established why one would have found it beneficial to utilize the disclosure in *Kobashi et al.* in the apparatus described in *Daoud et al.* Therefore, Claims 20-22 are further patentable over the cited prior art.

The Official Action addresses Claims 26-28 by referring to the disclosure in *Halpern*. These claims recite, for example, an operator card reader for reading discrete information on a card used to identify the operator of the apparatus to prevent unauthorized use, and a patient card reader for reading discrete information on a patient card used to identify the patient so that the patient can be identified by presentation of the patient card to the patient card reader. As the apparatus at issue here involves conditioning blood, these aspects of the claimed apparatus are important from the standpoint of, for example, correctly correlating conditioned blood with the patient that was the original source of the blood. However, as the apparatus described in *Daoud et al.* is merely used to gas-supersaturate physiologic saline or lactated ringers solution, there exists no reason why an ordinarily skilled artisan would have been led to add an operator card reader and patient card reader (and a printer) to the apparatus described in *Daoud et al.* Absent such rationale, a *prima facie* case of obviousness has not been established and Claims 26-28 are further allowable for at least these reasons.

It is believed that this application is now in a condition for allowance and such action is respectfully requested.

In the event the Examiner has any questions concerning this application, or if the Examiner believes a telephone conference with the undersigned would be helpful

in resolving any remaining issues pertaining to this application, the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

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Date: June 23, 2006

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